

*fb cont* <sup>25</sup>  
28. A method according to any one of claims <sup>12 18</sup>~~7, 14~~ and <sup>19</sup>~~18~~ wherein the formoterol component and the budesonide component are administered simultaneously.--

REMARKS

Claims 1, 2, 7 and 14-23 are pending in the application. Claims 1, 2, 7, 17, 20, 22 and 23 have been amended. Claim 19 has been cancelled. New claims 24-28 have been added. No new matter has been introduced by any of the claim amendments or added claims.

In the Attachment to Advisory Action mailed February 21, 1996, the Examiner indicated that the evidence provided in the Trofast Declarations received June 12, 1995 and January 16, 1996 is persuasive of the patentability of claims reciting a range of formoterol-to-budesonide molar ratios with an upper limit of 1:60. The Examiner has maintained the stance that the upper limit recited in the specification, i.e., 1:70, is not patentable absent a direct showing of the effectiveness of such a ratio.

Applicants disagree with the Examiner's assessment, reiterating their contention that the data demonstrate on their own a clear trend that makes credible to one of skill in the art the disclosed synergistic effectiveness of a 1:70 formoterol-to-budesonide ratio. Furthermore, the data meet the criteria set forth in the previously cited case

law with regard to establishing a trend that allows expansion of the scope of claims beyond what the data specifically show. However, in the interest of expediting prosecution of the subject application, claims 1, 2 and 7 have been amended to recite compositions and methods with an upper limit of 1:60 for the molar ratio of formoterol to budesonide. Applicants reserve the right to prosecute subject matter of the scope originally disclosed in a continuation application.

Claim 17 has been amended to make it an independent claim. Claims 20, 22 and 23 have been amended to delete their dependency from cancelled claim 19.

Support for new claims 24-26 can be found in the instant specification on, for example, page 7, lines 1-4; page 7, Example 1; and page 9, Example 3. Support for new claim 27 can be found on page 6, lines 31 and 32. Support for new claim 28 can be found, for example, from page 5, line 35 to page 6, line 3.

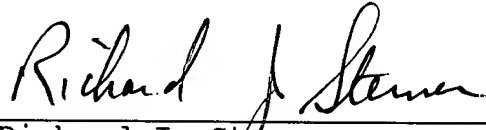
Based on the above, the claims are directed to patentable subject matter and are in condition for allowance. Reconsideration and allowance of pending claims 1, 2, 7, 14-18 and 20-27 are respectfully requested. Should any other matters require attention prior to allowance of the application, it is requested that the undersigned be contacted.

Accompanying this response are an Information Disclosure Statement, Form PTO-1449 and a copy of each reference listed thereon. Applicants respectfully request that the references be made of record in the application.

The Assistant Commissioner is hereby authorized to charge any fees due in connection with this communication to Deposit Account No. 23-1703.

Dated: August 29, 1996

Respectfully submitted,



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Enclosure